

REMARKS

Applicants respectfully request reconsideration of the present case in view of the above amendments and the following remarks.

Claims 1, and 3-11 are currently pending (claims 6-9 are withdrawn). Claim 2 has been canceled. Claims 1, 3, and 5 have been amended. Claims 10 and 11 have been added. No new matter has been inserted. Support for the amendment of claim 1 can be found in claim 2 and throughout the specification. Support for the amendment of claim 3 can be found at least at page 7, lines 28-30. Claim 5 was simply amended for clarification. Support for new claims 10 and 11 can be found in the specification at least in Figure 14.

The specification was objected to for not disclosing the specific sequence of the chicken myoD or the CDK4 used in the working examples. With regard to chicken myoD, Applicants point out that page 31, line 20 of the specification provides that clone CMD1 of chicken MyoD was used and that page 9 of the specification provides that chicken myoD (CMD1) is described in GenBank Accession No. L34006 (corresponding to Dechesne et al., 1994, *Mol. Cell. Biol.*, 14(8): 5474-86). Therefore, Applicants assert that one of skill in the art would recognize that the chicken myoD used in the examples is adequately disclosed. With regard to CDK4, Applicants point out that page 33, lines 23-25 of the specification describes that binding experiments were performed with CDK4 produced in the baculovirus system and refer to Kato et al., 1993, *Genes Dev.*, 7(3):331-42, which describes murine CDK4. Therefore, Applicants assert that one of skill in the art would recognize that the CDK4 used in the examples is adequately disclosed. Applicants respectfully request that this objection be withdrawn.

Claims 1-5 were objected to for failing to recite a sequence identifier number for the elected sequence, Tyr-Ser-Gly-Pro-Pro-Ser-Gly-Ala-Arg-Arg-Asn-Cys-Tyr-Glu. In response, Applicants point out that claims 1 and 3 have been amended to refer to SEQ ID NO: 1 corresponding to the sequence Tyr-Ser-Gly-Pro-Pro-Xaa-Xaa-Xaa-Arg-Arg-Xaa-Asn-Xaa-Tyr-Xaa, which encompasses the elected sequence. Applicants respectfully request that this objection be withdrawn.

35 U.S.C. § 112

Claims 1-5 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully traverse this rejection.

Specifically, the Examiner alleges that the term "CDK-4" is indefinite. While not conceding the correctness of the Examiner's position, in the interest of advancing prosecution, Applicants have amended claims 1, 3, and 5 to obviate this rejection. Specifically, Applicants have removed the term CDK-4. Applicants note that the claims now include the term "cyclin-dependent kinase 4" that is well understood by those of skill in the art. Applicants respectfully request that this rejection be withdrawn.

Claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph, as not enabled. Applicants respectfully traverse this rejection.

The Examiner alleges that the specification is not enabling for any peptide having the sequence "Tyr-Ser-Gly-Pro-Pro-Xaa₁-Xaa₂-Xaa₃-Arg-Arg-Xaa₄-Asn-Xaa₅-Tyr-Xaa₆, wherein Xaa₁= Cys or Ser; Xaa₂= Ser or Gly; Xaa₃= Ser, Ala or Pro; Xaa₄=Arg or Gln; Xaa₅= Ser, Cys or Gly; and Xaa₆=Asp or Glu". In response, Applicants assert that sufficient guidance is provided on the structure and function of the featured peptide to fully enable one of skill in the art to practice the full scope of the invention as claimed without undue experimentation.

First, Applicants have determined which residues are required for the desired cyclin-dependent kinase 4 binding activity. Specifically, in Example XI (pages 33-34), Applicants have shown that the 15-residue region from residues 189-203 of MyoD is the region responsible for binding to cyclin-dependent kinase 4. It was found that this fifteen amino acid domain bound to cyclin-dependent kinase 4 as efficiently as the full length MyoD peptide (see p. 33, lines 3-5).

Second, Applicants have identified those residues in the 15-residue peptide that are conserved across different species. In Figure 14, it is shown that the consensus sequence across Chicken, Human, Rat, Mouse, and Pig is "Tyr-Ser-Gly-Pro-Pro-Xaa₁-Xaa₂-Xaa₃-Arg-Arg-Xaa₄-Asn-Xaa₅-Tyr-Xaa₆". Applicants point out that it is a basic tenet of molecular biology that "the preservation of a consensus (sequence) implies that the sequence is functionally important. See Alberts et al., *Molecular Biology of the Cell 4th Ed.*, 2002, G:9 (copy attached). Therefore,

because the 15-residue sequence claimed in claims 1 and 3 is preserved across five different species, one of skill in the art would believe that this sequence is important to the cyclin-dependent kinase 4 binding function of this peptide. Further, as claimed in claims 1 and 3, Applicants have defined Xaa₁, Xaa₂, Xaa₃, Xaa₄, Xaa₅, and Xaa₆ to include those residues found in at least one of Chicken, Human, Rat, Mouse, and Pig.

Third, Applicants have amended the claims to specifically describe the activity of the peptide. That is, claims 1 and 3 require that the peptide binds to cyclin-dependent kinase 4. Cyclin-dependent kinase 4 is a specific peptide that is well known to those of skill in the art. For these reasons, Applicants submit that the specification enables one of skill in the art to practice the full scope of the pending claims. Applicants respectfully request that this rejection be withdrawn.

Claims 1-5 were also rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Applicants respectfully traverse this rejection.

The Examiner alleges that the specification only teaches the structure of a single representative species. However, Applicants draw the attention of the Examiner to Figure 14 where five different species of the 15-residue sequence are shown along with a consensus sequence between them. Specifically, the consensus sequence across Chicken, Human, Rat, Mouse, and Pig is shown to be "Tyr-Ser-Gly-Pro-Pro-Xaa₁-Xaa₂-Xaa₃-Arg-Arg-Xaa₄-Asn-Xaa₅-Tyr-Xaa₆". Therefore, Applicants have demonstrated five different species within the genus claimed. For this reason, Applicants assert that the specification provides sufficient description such that one of skill in the art would recognize that Applicants were in possession of the claimed invention. Applicants respectfully request that this rejection be withdrawn.

Further, the Examiner alleges that the claims are directed to polypeptides that have the function of binding to a genus or proteins having "CDK4 activity". In response, Applicants point out that claims 1 and 3 now refer to a peptide that binds "cyclin dependent kinase 4". Cyclin dependent kinase 4 is a specific peptide that is known to those of skill in the art.

Therefore, Applicants believe this rejection is now moot and respectfully request that it be withdrawn.

35 U.S.C. § 102(b)

Claim 1 was rejected under 35 U.S.C. § 102(b) as anticipated by Pearson-White et al., 1991. Applicants respectfully traverse this rejection.

While not conceding the correctness of the rejection, Applicants have amended claim 1 to include the features of claim 2, rendering this rejection moot. Applicants respectfully request that this rejection be withdrawn.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date



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